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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,202	09/14/2004	Sven Moesgaard	258563US0PCT	5104

22850 7590 03/05/2007

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EXAMINER	
MCCORMICK, MELENIE LEE	
ART UNIT	PAPER NUMBER
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/05/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/05/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/507,202	MOESGAARD ET AL.	
	Examiner	Art Unit	
	Melenie McCormick	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 8-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of preparing a selenium yeast product and the product obtained therefrom, from the particular species of Saccharomyces disclosed (see. e.g. claims 5-7), does not reasonably provide enablement for such methods and products which are obtained from the large number of species which are part of the yeast family. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have reasonably demonstrated/disclosed that the instantly claimed method of obtaining a selenium yeast product and the product obtained therefrom obtained from particular species of yeast (see e.g. claims 5-7) may be useful for the intended uses instantly claimed (i.e. use in a nutritional supplement). However, the claims encompass using any and all species of yeast for such purpose. This is clearly beyond the scope of the

instantly claimed/disclosed invention, as applicants have not disclosed that they have tested any and all specie of yeast for their ability to produce such a product. It should be noted that there are 1,500 species of yeast (as referenced by wikipedia.com). As further referenced by Wikipedia.com, different types of yeast have different requirements for growth and nutrition (see e.g. page 2).

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to perform the instantly claimed method of preparing a selenium yeast product for use in a nutritional supplement from among the large number of yeast species encompassed by the instant claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite because the claim language is overall confusing. The claim is drawn to a method for preparing a selenium yeast product. If the claim parts ii), iii), and iv) are intended to be steps performed during this method, it is suggested that they are re-written to reflect this. As currently drafted, ii), iii), and iv)

appear to be experimental conditions, rather than method steps. This is confusing because claim parts i) and v) appear to be method steps.

Claim 1 is also rendered vague and indefinite by the broad range followed by the more narrow range in steps iii) and iv). A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In the present instance, claim 1 recites the broad recitation "1%", and the claim also recites "preferably 0.5% and most preferably 0.2%" in iii), which is the narrower statement of the range/limitation.

Claim 1 also recites the limitation between "4.0 and 6.0", and the claim also recites "preferably between 4.4 and 5.7, most preferably between 4.7 and 5.4, such as 5.0", which is a narrower statement of the range/limitation.

Claim 4 is also rendered vague and indefinite because it recites "A method according to claim 1 further comprising" and then recites an experimental condition rather than a method step.

Claim 5 is also rendered vague and indefinite because it also recites "A method according to claim 1 further comprising" and then recites an experimental condition rather than a method step.

Claim 7 is rendered vague and indefinite for reciting a broad range followed by a narrow range. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent

protection desired. In the present instance, claim 7 recites the broad recitation "a content of organic selenium compounds corresponding to a range of between 1000 and 1600 ppm of selenium", and the claim also recites "preferably between 1100ppm and 1500ppm of selenium, most preferably between 1200 ppm and 1400 ppm of selenium" which is the narrower statement of the range/limitation.

Claim 7 recites the limitation "the content of l-selenomethionine" " in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 is further rendered vague and indefinite because each of the part (a, b, and c) appear to be different things. Part a) appears to be a component of the selenium yeast product, part b) appears to be a characteristic of the selenium yeast product, and part c) appears to be a method of obtaining the selenium yeast product. Because the claim recites a selenium yeast product comprising: it is assumed that each of a), b), and c) will recite components of the yeast product.

Claim 7 is further rendered vague and indefinite by the phrase "raw materials which are described in pharmacopoeia" in part c. This phrase does not adequately describe the materials used.

Claim 8 is rendered vague and indefinite because the phrase " a selenium yeast product according to claim 7, comprising producing said selenium yeast product" is awkward and does not describe the selenium yeast product.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nogadawithana et al. (US 4,530,846).

The claims are drawn to a selenium yeast product comprising a content of organic selenium compounds corresponding to a range of between 1000 and 16000 ppm of selenium, wherein the content of L-selenomethionine constitutes at least 55% of the total selenium content and the content of selenium in inorganic selenium compounds does not exceed 1% of the total selenium content.

Nogadawithana et al. disclose an edible selenium yeast product (see e.g. col 6-Example 7) which appears to be identical to the presently claimed extract composition, since it was extracted via the same essential steps as instantly claimed - i.e. providing yeast with the proper amounts of nutrients and selenium under aerobic conditions and

isolating the yeast obtained therefrom (see e.g. claim 1). In addition, the extract composition of Nogadawithana et al. is used as a nutritional supplement (as instantly claimed) - see e.g. claim 1. Consequently, the claimed selenium yeast product composition appears to be anticipated by the reference.

In the alternative, even if the claimed extract composition is not identical to the referenced extract composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced extract composition is likely to inherently possess the same characteristics of the claimed extract composition particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed extract composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

With respect to the art rejection above, please note that "the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nogadawithana et al. (US 4,530,846) and Demicri et al. (J. Agric. Food Chem.), in view of Schrauzer (Journal of Nutrition).

A method of preparing a selenium yeast product and the selenium yeast product obtained therefrom are claimed.

Nogadawithana et al. beneficially teach a method of obtaining a selenium yeast product. Nogadawithana et al. further teach that the method includes the steps of cultivating yeast under aerobic conditions, supplying the yeast with a carbon source, nutrients, and a selenium salt in an amount within the range instantly claimed (1000 ppm) (see e.g. claim 1, step c). The method taught by Nogadawithana et al. further comprises the step of isolating (recovering/separating) the selenium yeast, washing,

heat treating (pasteurizing), and drying the yeast (see e.g. claim 1, steps d-f and col 5, lines 24-30). It is also disclosed that the optimal pH for this process is 5.2, which is within the range instantly claimed (see e.g. col 5, line 17). Nogadawithana et al. also disclose that the method is performed using *Saccharomyces cervisiae* (see e.g. claim 10) and that the inorganic selenium compounds are less than about 0.5% (which does not exceed 1% of the total selenium content) (see e.g. claim 12). Nogadawithana et al. do not explicitly teach that the L-selenomethionine constitutes at least 55% of the total selenium content in the product, however, as evidenced by Schrauzer, yeasts such as *Saccharomyces cervisiae* contain more than 90% of the total selenium in the form of L-selenomethionine (see e.g. page 1653, -Biosynthesis). Therefore, the yeast product obtained by the method taught by Nogadawithana et al. would intrinsically contain L-selenomethionine in an amount which constitutes at least 55% of the total selenium content.

Nogadawithana et al. also do not explicitly teach that the sole carbon source is glucose, or that minimal medium is used.

Demicri et al. beneficially teach a method of making selenium yeast as a source of bioavailable selenium (i.e. for use as a nutritional supplement) (see e.g. page 2491). Demicri et al. further teach that the method comprises the use of what would be considered a minimal medium and glucose as the carbon source (see e.g. page 2492-Stock media preparation).

It would have been obvious to one of ordinary skill in the art to prepare a selenium yeast product in the manner instantly claimed. One of ordinary skill in the art

at the time the claimed invention was made would have been motivated and would have had a reasonable expectation of success in doing so based upon the beneficial teaching of Nogadawithana et al. that such a product has been prepared in essentially the same manner as instantly claimed for the same purpose (use as a nutritional supplement). It would further have been obvious to one of ordinary skill in the art at the time the claimed invention was made to alternatively utilize a minimal medium and glucose as the sole carbon source, as beneficially taught by Demicri et al., in the method disclosed by Nogadawithana et al. One of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success in doing so based upon the disclosure of Nogadawithana et al. that the carbon source may be a carbohydrate (see e.g. claim 7) (i.e. glucose), and fact the products obtained from each of the methods are useful as nutritional selenium sources.

One of ordinary skill in the art at the time the claimed invention was made would have realized that a product intended for use as a nutritional supplement would need to be produced using pharmaceutical grade materials, and thus would have used such materials in the methods disclosed by Nogadawithana et al. and Demicri et al. It would have also been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the selenium product beneficially taught by Nogadawithana et al. to a food product, dietary supplement or drug based upon the beneficial teaching of Schrauzer that selenium is necessary in human and animal nutrition and that selenised yeast and selenomethionine are suitable for selenium supplementation, as selenomethionine is a bioavailable source of selenium (see e.g. page 1653). The

addition of essential nutrients (such as the selenomethionine present in the selenium yeast product disclosed by Nogadawithana et al. to food, dietary supplements, and drugs is well known in the nutrition art. The adjustment of particular conventional working conditions (e.g. the adjustment of particular experimental conditions such as the concentration of ethanol present during the cultivation or the particular method of recovering/separating the yeast (i.e. centrifugation or filtration)) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.